

Wet Bacterial Penetration Testing Final Report

Test Article: Product Name: Disposable Medical Protective Gown
Model: ZKF-01
Lot No: 2020080503
Purchase Order: QHT20080426
Study Number: 1340488-S01
Study Received Date: 11 Sep 2020
Testing Facility: Nelson Laboratories, LLC
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: STP0188 Rev 02
Deviation(s): None

Summary: This test method was written to comply with ISO22610:2006, and uses an electrically driven turntable to rotate an agar plate while a vertical finger presses on a material inoculated with bacteria. The inoculated material, called the donor, lies on top of the test article. The finger is moved over the entire surface of the plate at a rate of 60 revolutions per minute for 15 minutes. The finger exerts a 3 Newton force on the agar plate. Due to the effect of rubbing and liquid migration, bacteria can pass from the donor through the test specimen down to the agar plate. The results characterize the barrier capability and the penetration over time of the test article. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Article Side Tested: Outside
Test Article Preparation: 25 cm x 25 cm squares were aseptically cut from the Critical Chest Material and Sleeve Seams at Random
Temperature During Testing: 21.9°C
Relative Humidity During Testing: 26%
Staphylococcus aureus #29213 Titer: $\sim 2.4 \times 10^4$ CFU/mL

Janelle Bentz electronically approved
Study Director

Janelle Bentz

14 Oct 2020 15:59 (+00:00)
Study Completion Date and Time

Results:
Chest:

	Colony Counts (CFU)				
	Replicate #1	Replicate #2	Replicate #3	Replicate #4	Replicate #5
Plate #1 (X ₁)	0	0	0	0	0
Plate #2 (X ₂)	1	0	0	0	0
Plate #3 (X ₃)	1	0	0	0	0
Plate #4 (X ₄)	0	0	3	2	1
Plate #5 (X ₆)	1	0	9	4	0
Plate #6 (Z)	9	24	17	26	28

Calculations

T	12	24	29	32	29
C _{BP}	2.17	0.50	0.75	0.83	1.50
I _B	5.3	6.0	5.5	5.8	5.9

CFU = Colony forming units

T = estimated bacterial challenge

 C_{BP} = Barrier Penetration Coefficient

 I_B = Barrier Index

Sleeve Seam:

	Colony Counts (CFU)				
	Replicate #1	Replicate #2	Replicate #3	Replicate #4	Replicate #5
Plate #1 (X ₁)	0	0	0	0	0
Plate #2 (X ₂)	0	0	0	0	0
Plate #3 (X ₃)	0	0	0	0	0
Plate #4 (X ₄)	0	0	0	0	0
Plate #5 (X ₆)	0	0	0	1	1
Plate #6 (Z)	69	44	~184	53	123

Calculations

T	69	44	~184	54	124
C _{BP}	0.50	0.50	~0.50	0.50	0.50
I _B	6.0	6.0	~6.0	6.0	6.0

Test Method Acceptance Criteria: The challenge titer must be 1.0×10^4 to 4.0×10^4 CFU/mL. The force applied must be 3 ± 0.02 Newtons (N). The duration of the test must be 15 minutes \pm 10 seconds per plate.

Interpretation of Results: Performance requirements for surgical gowns and drapes per EN 13795:2019+A1:2013:

Characteristic	Test Method	Unit	Requirement			
			Standard Performance		High Performance	
Resistance to microbial penetration - Wet	EN ISO 22610	I _B	Critical Product Area	Less Critical Product Area	Critical Product Area	Less Critical Product Area
			≥2.8	Not required	6.0	Not required

Procedure: This test method was validated at Nelson Laboratories, LLC and included carbon paper and reference material checks per ISO 22610.

One mL of *S. aureus*, ATCC #29213 was dispensed and evenly spread over a carrier material which was a polyurethane (PU) film in compliance with ISO 22610. The donor (contaminated carrier) was dried at approximately 56°C, spreading the liquid suspension at even intervals until dry. The donor was placed with the inoculated side down, onto the test side of the test article. A high density polyethylene (HDPE) film was placed on top of the donor for protection. An outer steel ring was placed over the entire setup: inner steel ring, test article, donor and HDPE film so that all materials were clamped and held securely. The test assembly was placed onto an agar plate which had a distance from the surface of the agar to the rim of the petri dish of 3 ± 0.2 mm. An abrasion resistant finger at a force of approximately 3 N was placed on top of the HDPE/donor/test article configuration. For 15 minutes the finger moved around the entire surface of the plate at 60 revolutions per minute so that only a small area was brought into contact with the agar surface at a time. Five approximate 15 minute tests were performed with the same donor and test article. Each 15 minute test uses a new agar plate each time, allowing for an estimation of penetration over time. The bacterial challenge on the test side of the test article was inverted so the test side faced the agar. Once inverted, another 15 minute test was performed to estimate the bacterial challenge. The agar plates were incubated for 48 ± 4 hours at $36 \pm 1^\circ\text{C}$.

Counting and Calculations: After incubation, the plates were counted disregarding colonies within 15 mm around the center of the plate. The calculations were performed as follows:

$$T = Z + X_1 + X_2 + X_3 + X_4 + X_5$$

$$R_{\text{CUM1}} = \frac{X_1}{T}$$

$$R_{\text{CUM2}} = \frac{(X_1 + X_2)}{T}$$

$$R_{\text{CUM3}} = \frac{(X_1 + X_2 + X_3)}{T}$$

$$R_{\text{CUM4}} = \frac{(X_1 + X_2 + X_3 + X_4)}{T}$$

$$R_{\text{CUM5}} = \frac{(X_1 + X_2 + X_3 + X_4 + X_5)}{T}$$

$$C_{\text{BP}} = \frac{(R_{\text{CUM1}} + R_{\text{CUM2}} + R_{\text{CUM3}} + R_{\text{CUM4}})}{R_{\text{CUM5}}} + \frac{1}{2}$$

$$I_B = 6 - \left[(C_{\text{BP}} \times R_{\text{CUM5}}) + \frac{R_{\text{CUM5}}}{2} \right]$$

- Z = The number of colonies from the top side (plate 6) of the test specimen that are left over after the 5 agar plates have been run, measured on the 6th agar plate.
- X₁, ..., X₅ = The number of colonies on the 5 plates in one replicate test, using the same test specimen and donor.
- R_{CUM1}, ..., R_{CUM5} = The cumulative penetration ratio of plates 1 to 5.
- R_{CUM5} = An estimate of the fraction of the bacterial challenge that has penetrated the barrier.